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REMARKS

The issues outstanding in the Office Action mailed November 18, 2002, the rejections under 35 U.S.C. §112 and §103. Reconsideration of these issues, in view of the following discussion is respectfully requested.

Rejections Under 35 U.S.C. §112

Claims 1-23 remain rejected under 35 U.S.C. §112, first paragraph. It is argued that these claims are not enabled. Applicants respectfully disagree.

At pages 2-4 of the Office Action, various factors are set forth which are alleged to support the conclusion of non-enablement. Careful consideration of these factors, belies this conclusion.

1. There is apparently confusion as to the nature of the invention, inasmuch as various gestagens are listed as if they were estrogens at page 2 of the Office Action. The paragraph labeled "1" in this portion of the Office Action lists drospirenone, cyrosterone and dienogest as estrogens, whereas they are, in fact, gestagens. Moreover, this paragraph lists "gestagen" as an estrogen. Independent claim 1 recites administration of a gestagen, independent claim 3 a gestagen and an estrogen, and independent claim 24 recites administration of a gestagen which is dropirenone.

2. It is argued in this portion of the Office Action that the difference between PMDD and PMS is symptomology. In fact, this is an over-simplification. As discussed in the previous Declaration Under 37 C.F.R. §1.132, PMDD is a distinct clinical disorder with a distinct clinical picture that is distinguished from PMS *not* just by severity of symptoms, but by the number and character of symptoms, and also on the basis of response to pharmacological treatment. As discussed in the declaration, PMDD responds to pharmacologic treatment, whereas PMS does not.

3. At page 3 of the Office Action, without any basis whatsoever, it is stated that predicting which gestagen or its combination with any estrogen would be useful in the treatment of PMDD is "impossible." This is absolutely untrue, in view of the relatively simply screening

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tests known in the art, as well as that given at page 9 of the specification. Moreover, the Office Action has not advanced any basis to doubt that any given gestagen would be effective. See *In re Marzocchi*, 439 F.2d 220, 109 USPQ 367 (CCPA 1971). In the absence of such basis, the objective enablement in the specification is sufficient.

4. While the Office Action apparently dislikes the working example, which demonstrates "significant improvement" in various symptoms based on the combination of a gestagen and estrogen, it is submitted that the choice of terms used in the examples is not a basis for objection. Because the symptoms are subjective, subjective description must be used in evaluating them. The examples clearly show an improvement and are thus probative. The Office Action should not substitute its judgment for that of the ordinary skilled artisan.

There is no paragraph 5 in the Office Action.

6. With respect to the breadth of the claims, near breadth alone is insufficient to support non-enablement. See *Marzocchi, supra*. Moreover, note new independent claim 24 directed to drospirenone. Moreover, the "significance" of the progesterone treatment disclosed in Dennerstein, discussed at page 3 of the Office Action, undercuts the point which is attempted to be made. Specifically, Dennerstein shows that some effective treatment for PMS *are* available. To the extent that the Office Action persist in arguing that PMS and PMDD are the same, this would support the argument for enablement.

7. This paragraph of the Office Action attempts to piggy back undue experimentation on to unpredictability. This is impermissible. See *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988).

As further evidence of the enablement of the claims, attention is directed to Freeman et al., J. Women's Health Gend. Based Med. 10(6) 2001, pp. 561-9. In this article, the authors demonstrate the beneficial effect of drospirenone and an estrogen on PMDD. (The article is supplied with the IDS filed herewith; the article is post-published and does not constitute prior art. One of the authors is employed by the U.S. subsidiary of the assignee of the present application.) This article, while post-published, clearly supports applicants' position that the presently claimed process is effective. The use for such purpose of material published after applicants' filing date is, of course, permissible. See *EnzoBiochem, Inc. v Calgene, Inc.*, 188

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F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1998).

In conclusion, it is submitted that the claims are fully enabled, and withdrawal of this rejection is respectfully requested.

Rejection Under 35 U.S.C. §103

Claims 1-23 have been rejected under Dennerlein et al. taken with Goldberg. Reconsideration of this rejection is respectfully requested. As discussed previously, these references are directed to PMS. Thus, in view of the expectation in the art that PMDD does not respond to conventional treatment, these references are irrelevant. Withdrawal of the rejection is therefore respectfully requested.

The claims of the application are submitted to be in condition for allowance. Should the Examiner have any questions or comments, she is cordially invited to telephone the undersigned at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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Attorney/Agent for Applicant(s)

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FILED: May 19, 2003

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Name: Blanca R. Smith
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Date: May 19 2003

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Norman NASHED et al.

Serial No.: 09/619,493 Group Art Unit: 1616

Filed: July 19, 2000 Examiner: S.N. Qazi

For: THERAPEUTIC GESTAGENS FOR THE TREATMENT OF PREMENSTRUAL DYSPHORIC DISORDER

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees

☐ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:

- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
- ☐ within three months of the actual filing date of the national phase of a PCT application; OR
- ☐ before the mailing of a first substantive office action (including after filing of an RCE).

☒ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:

- ☒ a final rejection under 37 C.F.R. 1.113;
- ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
- ☐ a notice of allowance under 37 C.F.R. § 1.311; and

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is accompanied by:

☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR

☒ a check covering the fee of $180.00 under 37 C.F.R. § 1.17(p).

☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:

☐ a final action under 37 C.F.R. § 1.113;

☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR

☐ a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

☐ the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of $180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or

☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. _____, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).

☐ Copies of materials listed but not attached were cited in an international search report dated _____.

☐ Copies of the materials listed are attached (except for the foregoing).

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Non-English Language References

☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).

☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone
Y = document of particular relevance when it is combined with another such document
A = document defining the general state of the art
O = non-written disclosure
P = intercalated document
T = document cited to understand the theory or principle underlying the invention
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date
D = cited in the application
L = cited for another reason
& = publication of member of same patent family

☐ Translation of other relevant information on foreign search report

[insert necessary translation here]

Other Information

Payment of Fees Due (If Any):

☒ A check for $180.00 covering the fee identified above is attached.

☐ Please charge to Deposit Account No. 13-3402 $ for the fee identified above.

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☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,

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FILED: May 19, 2003

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	09/619,493
Filing Date	July 19, 2000
First Named Inventor	N. NASHED et al
Group Art Unit	1616
Examiner Name	S.N. Qazi
Attorney Docket Number	SCH 1686 C1

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY

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Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 2

Complete if Known	
Application Number	09/619,493
Filing Date	July 19, 2000
First Named Inventor	N. NASHED et al.
Group Art Unit	1616
Examiner Name	S.N. Qazi
Attorney Docket Number	SCH 1686 C1

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog etc.) date, page(s) volume-issue number(s), publisher city and/or country where published.	T [2]
	B1	E. Freeman et al., *Evaluation of a Unique Oral Contraceptive in the Treatment of Premenstrual Dysphoric Disorder*, Journal of Women's Health & Gender-Based Medicine, Vol. 10, No. 6, 2001, pp. 561-569	
	B2	E. Freeman et al., *A Double-blind Trial of Oral Progesterone, Alprazolam, and Placebo in Treatment of Severe Premenstrual Syndrome*, JAMA, Vol. 274, No. 1, July 5, 1995, pp. 51-57	
	B3	P.M. O'Brien et al., *Treatment of Premenstrual Syndrome by Spironolactone*, British Journal of Obstetrics and Gynaecology, Vol. 86, February 1979, pp. 142-147	
	B4	D. Hellberg et al., *Premenstrual tension: a placebo-controlled efficacy study with spironolactone and medroxyprogesterone acetate*, Int. J. Gynecol. Obstet., 1991; 34: pp. 243-248	
	B5	M. Wang et al., *Treatment of premenstrual syndrome by spironolactone: A double-blind, placebo-controlled study*, Acta Obstet Gynecol Scand. 1995. 74: pp. 803-808	
	B6	R.B. Burnet et al., *Premenstrual Syndrome and Spironolactone*, Aust NZ J. Obstet Gynaecol 1991, 31 4: 366	
	B7	K. Aslasksen et al., *Spironolactone in the Treatment of Premenstrual Tension: A Double-Blind Study of Spironolactone Versus Bendroflumethiazide and Placebo*, Current Therapeutic Research, Vol. 49, No. 1, January 1991, pp. 120-130	

Examiner Signature		Date Considered	

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